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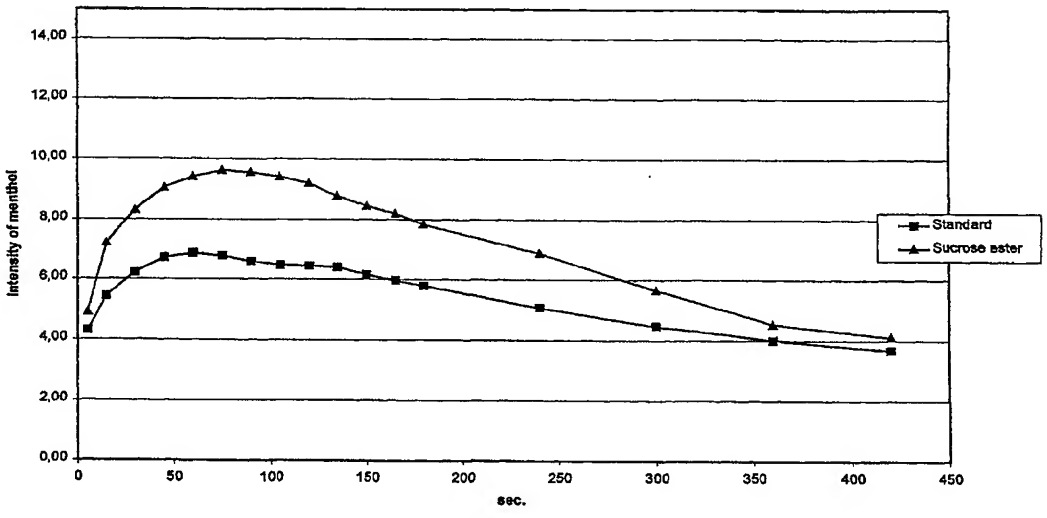

(57) Abstract

The present invention relates to the use of a fatty acid sucrose ester wherein at least 40% of the fatty acid is palmitate for increasing release of an active ingredient from a product selected from beverages, foodstuff, including functional foods, candy, and oral pharmaceutical compositions including products for the oral cavity. The invention furthermore relates to a chewing gum formulation having increased release of an active ingredient and which comprises at least 0.01% of said sucrose fatty acid ester, and to a method for the preparation of a chewing gum. The active ingredient is preferably a flavour and/or a pharmaceutical active ingredient.

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Sucrose fatty acid esters for use as increased release of active ingredient.

The present invention relates to use of specific sucrose fatty acid esters for increasing the release of flavour or other active ingredients in oral pharmaceutical compositions, foodstuff, beverages, candy, and especially in chewing gum. With respect to flavours, the release by use of the fatty acid esters according to the present invention results in surprising increased properties with respect to flavour sensation. The sucrose fatty acid esters according to the present invention is furthermore used for increased or accelerated controlled release of active agents in a chewing gum composition and in other oral pharmaceutical formulations

Technical Field

The present invention relates to use of a sucrose fatty acid ester to increase release of active ingredients such as flavour and pharmaceutical active ingredients. The increased release of flavour and other active ingredient results in superior properties in chewing gum, oral pharmaceutical compositions, foodstuff, beverages and candy. The invention also relates to products comprising such sucrose fatty acid esters which products have increased properties with respect to flavour such as increased cooling effect and flavour intensity. The invention furthermore relates to a process for the preparation of a chewing gum composition comprising the specific sucrose fatty acid esters.

In recent years extensive research has been carried out with respect to the use of chewing gum as a delivery system for medicines. This delivery system has proven especially suitable when a local effect in the oral cavity or the pharynx is desired or when an absorption of the medicine via the mucous membrane of the mouth is required in such cases when it is desirable to avoid the so-called "first pass" effect, that is the catabolism in the liver at the first passage, or when the medicine is sensitive to the environment in the gastro-intestinal tract.

Several methods have been provided for the preparation of a chewing gum composition capable of releasing specific components in a controlled manner. Thus, a number of processes are known for obtaining an improved release of specific aroma agents and highly potent sweeteners with the purpose of prolonging the perception of taste when chewing a chewing gum.

US patent No. 4,238,475 discloses a chewing gum comprising a water-insoluble thereapeutic component which is coated with a water-soluble coating agent to prevent resorption of the therapeutic component back into the gum base. The release of the therapeutic component is, however, conditional on the coating remaining intact during the chewing. As a result, the therapeutic component does not come into direct contact with the oral cavity and cannot therefore be used for medicines intended to be locally effective in the oral cavity and the pharynx. Furthermore, the method of preparation is elaborate and further complicated by the fact that the coating must not be destroyed during the preparation.

EP patent application No. 227,603 discloses a chewable delivery system comprising an active agent coated with lecithin, polyoxyalkylene, glyceride etc and then incorporated in a matrix system comprising among other things gelatine, water and sweetener. Also in this case the active agent passes through the oral cavity in a coated form and will therefore not produce a local effect.

EP patent application No. 229,000 discloses a process and a chewing gum for the protection and controlled release of an active agent, including medicine, highly potent sweeteners and aroma agents. The active agent is provided with a hydrophobic coating using a melt blend of polyvinyl acetate and plasticizer whereupon the blend is cooled, ground, sieved and blended with usual chewing gum ingredients. It is stated that a delayed release in the order of 10 to 20 minutes can be obtained, but this does, however, not automatically result in an increase of the total quantity of substances released. The process is rather complicated and requires the active agent to be able to stand the temperatures involved in the process.

EP patent application No. 217,109 discloses a chewing gum in which prolonged and controlled release of, among other things, pharmaceutical agents, food ingredients and confectionery ingredients in multi-micro encapsulation hereof is obtained by means of, for instance, cellulose compounds, polyvinyl pyrrolidone, starch or saccharose etc. The process is, however, complicated and difficult to control.

US patents Nos. 4,493,849 and 4,597,970 disclose that lecithin can be used in chewing gum to improve the mouthfeel of the chewing gum and to increase the moistening properties and texture.

DK patent application No. 5386/83 discloses a method for obtaining longer impact times in the oral cavity when treating fungal infections in the oral cavity. This is obtained by formulating antifungally active compounds, especially imidazole and triazole derivatives, with special gel agents such as cellulose ethers, sodium alginate and propyleneglycol alginate, in order to obtain a better adhesion of the active agent to the oral cavity. It is, however, unpleasant and difficult to keep such gelatinous preparations in the mouth for long and the impact of the active agent will vary considerably depending on how long it is kept in the mouth.

WO 97/00619 discloses use of sucrose fatty acid esters in chewing gum. The sucrose fatty acid ester is used in the gum or gum base as a plasticizer, softener, and emulsifier. The sucrose fatty acid ester is also used as replacement for fat, oils and emulsifiers, and it is mentioned that sucrose fatty acid esters may by used as a release agent for encapsulated flavours and as a carrier for flavour oils. The application relates to sucrose fatty acid esters as such including palmitic and stearate acids. There is no mentioning or indication that certain sucrose fatty acid esters should be superior with respect to any of the general use of sucrose fatty acid esters disclosed therein.

Sucrose esters are known for their emulsifying properties. Accordingly, they have been used in a broad spectrum of foodstuff.

Certain sucrose acid esters have been available from Sisterna C.V., Oosteliijke Havendiijk 15, The Netherlands. These sucrose acid esters include the compositions having a fatty acid ester content of stearate/palmitate comprising 70% stearate and 30% palmitate. The products have been available in compositions having 70%, 60% 50%, 40% 30% and 10% monoesters, respectively (commercially known as Sisterna SP 70, SP 60, SP 50, SP 40, SP 30, SP 20, and SP 10). The Hydrophile Lipophile Balance (HLB) values of the known sucrose fatty acid esters vary according to the content of monoesters. The higher the content of monoester the higher the HLB value. HLB value of SP 70 and SP 10 is 15 and 2 respectively. However, these commercial products do not have the improved properties according to the present invention

BRIEF DESCRIPTION OF THE INVENTION

Emulsifiers are among other properties in general believed to be essential for the distribution of flavours and other ingredients in formulations such as chewing gum. With

respect to chewing gum, emulsifiers have been mentioned as an important ingredient for distributing the expensive flavours resulting in formulations where the flavour to a higher degree is made available to the consumer.

It is a well-known problem in chewing gum preparation that only a small share of the aroma agents added are released from the chewing gum within the usual chewing period of 2 to 10 minutes. It is not unusual that the amount of aroma agent released stated as a percentage of the total quantity of aroma agent added, is of the following order:

After chewing for 2 minutes: 5 to 15%
After chewing for 5 minutes: 7 to 20%
After chewing for 10 minutes: 10 to 25%

Which means that a very large share, 75 to 90% of the aroma agents added is wasted when the chewing gum is thrown away. This is the reason why a relatively large quantity of aroma agents is used in chewing gum compared to other confectioneries. The aroma agents often being costly ingredients, the quantity of these in a chewing gum composition, although usually only present in a quantity of around 0.5 to 2.0%, is of great importance to the price and consequently to the competitiveness of the product.

The gum base of a chewing gum will also retain a substantial part of other ingredients such as pharmaceutical drugs, vitamins, and other active ingredients.

The benefit for the producer according to the present invention is therefore that less cost for the production as minor amounts of an active ingredient include flavours are needed for the same taste sensation or effectiveness. In the chewing gum production, the emulsifiers are generally used as softeners and also for reducing the stickiness of the gum formulation during and after the processing.

According to the present invention it has surprisingly been shown that use of certain related palmitate/stearate sucrose fatty acid esters having a composition wherein the palmitate content is higher than 30% based on the total fatty acid content have unexpected properties. These properties are also very surprising in light of the fact that sucrose fatty acids wherein the content of palmitate acid is 30% (and having similar content of monoesters) do not show such effect. In addition, it has been shown that the

properties are of special advantage with respect to certain flavour components and active ingredient.

The sucrose fatty acid esters according to the present invention relate to palmitate/stearate sucrose fatty acid esters wherein the palmitate content is higher than 30%. Preferably, the content of palmitate is 50% or more.

Use of these sucrose fatty acid esters has resulted in products wherein the flavour has been significantly increased. Both with respect to intensity of e.g. cooling and fruit flavour, but also with respect to altering the overall taste sensation. Accordingly, by use of the sucrose fatty acid esters of the present invention, new aspects of well-known flavours may be utilised. In one embodiment of the invention, the increased flavour intensity may be used as taste masking in oral compositions comprising active ingredients which by themselves has undesired taste or which alter the taste of the formulation.

In addition, active ingredients such as pharmaceutically active components may be effectively released from the chewing gum.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to use of a fatty acid sucrose ester wherein at least 40% of the fatty acid is palmitate for increasing release of an active ingredient from a product selected from beverages, foodstuff, including functional foods, candy, and oral pharmaceutical compositions including products for the oral cavity. The content of palmitate in the sucrose fatty acids ester is at least 40%, such as at least 60%, preferable at least 70%, more preferred at least 80%, still more preferred at least 90%, most preferred about 100%, still more preferred at least 90%, most preferred about 100%.

The products according to the present invention may in another embodiment comprise the palmitate in an amount between 50% and 100%, such as between 60% and 95%, preferable between 75% and 90% such as about 80%.

The preferred sucrose ester further comprises stearate and in a still more preferred embodiment, the fatty acids are stearate and palmitate as the only fatty acid esters. The esters may be a mixture of mono-, di, and tri-esters. In the preferred embodiment, the sucrose fatty acid ester comprises at least 10% monoesters, such as at least 20%,

preferable at least 30%, more preferred at least 40%, still more preferred at least 50%, most preferred about 60% monoesters. However, a high content of monoester may be an advantage and is furthermore correlated to the HLB-value. Accordingly, use wherein the sucrose fatty acid ester comprises at least 50% monoesters, such as at least 60%, preferable at least 70%, more preferred at least 80%, still more preferred at least 90%, most preferred about 100% monoesters are within the scope of the invention.

The use of a flavour as the active ingredient has surprisingly resulted in increased properties relating to increased intensity of the flavour and cooling. See also the examples in this respect wherein it is disclosed that the sucrose fatty acid ester further reduces the tac to the teeth. Volume is furthermore increased by the use according to the invention.

The products and use according to the invention include use of a pharmaceutically active ingredient together with at least one flavour. The flavour may then be released simultaneously with the pharmaceutical and thereby contribute to an taste masking effect.

The sucrose fatty acid ester is preferably used in an amount of from about 0.01 to 30% by weight of the total composition preferably in an amount from 0.1% to 20% by weight.

The product according to the invention may preferably be a candy, chewing gum, or an oral pharmaceutical composition. In the latter case, the active ingredient is a pharmaceutically active ingredient including ingredients for local treatment on the oral cavity or oral hygienic ingredients. The active ingredients are described in further detail below.

In a preferred embodiment, the use of a fatty acid sucrose ester according to the invention is for the preparation of a chewing gum, and the sucrose fatty acid ester is preferably added to the gum base of the chewing gum in an amount of about 0.03 to 30% by weight, preferable from 0.5 to 10 % by weight, more preferred in an amount of from 1-3% by weight, such as about 2% by weight of the gum base.

The invention also relates to a chewing gum formulation having increased release of an active ingredient and
comprising, a) an insoluble gum base; b) a water soluble portion; c) a flavour

d) at least 0,01% fatty acid sucrose ester wherein at least 40% of the fatty acid is palmitate.

The invention furthermore relates to a method for increasing the release of an active ingredient by use of a fatty acid sucrose ester as describe above.

The sucrose fatty acid esters of the present invention are preferable used in the gum base of chewing gum, or alternatively in the chewing gum formulation, or both in the gum base and chewing gum. In addition, the effect on the flavours may be used in any formulation or composition where an increased effect of taste or flavour is desired. Accordingly, the increased flavour properties identified according to the present invention may also be used for any product intended for oral consuming.

The aroma agents and flavours usable for the compositions according to the present invention are for instance natural and synthetic flavourings (including natural flavourings) in the form of freeze-dried natural vegetable components, essential oils, essences, extracts, powders, including acids and other substances capable of affecting the taste profile. Examples of liquid and powdered flavourings include coconut, coffee, chocolate, vanilla, grape fruit, orange, lime, menthol, liquorice, caramel aroma, honey aroma, peanut, walnut, cashew, hazelnut, almonds, pineapple, strawberry, raspberry, tropical fruits, cherries, cinnamon, peppermint, wintergreen, spearmint, eucalyptus, and mint, fruit essence such as from apple, pear, peach, strawberry, apricot, raspberry, cherry, pineapple, and plum essence. The essential oils include peppermint, spearmint, menthol, eucalyptus, clove oil, bay oil, anise, thyme, cedar leaf oil, nutmeg, and oils of the fruits mentioned above.

In a preferred embodiment, the flavour is one or more natural flavouring agent which is freeze-dried, preferably in the form of a powder, slices or pieces of combinations thereof. The particle size may be less than 3 mm, such as less than 2mm, more preferred less than 1mm, calculated as the longest dimension of the particle. The natural flavouring agent may in a form where the particle size is from about 3μm to 2 mm, such as from 4μm to 1 mm. The preferred natural flavouring agent comprises seeds from a fruit e.g. from strawberry, blackberry and raspberry, and which seeds are substantially intact.

Various synthetic flavours, such as mixed fruit may also be used according to the present invention. As indicated above, the aroma agent may be used in quantities smaller than

those conventionally used. The aroma agents and/or flavours may be used in an amount of from 0.01 to about 30 weight-% of the final product depending on the intensity of the aroma and/or flavour used. Preferably, the content of aroma/flavour is in the range of from 0.2 to 3% of the total composition.

The invention are suitable for increased or accelerated release of active agents selected among the group dietary supplements, oral and dental compositions, antiseptic agents, pH adjusting agents, anti-smoking agents, sweeteners, flavourings, aroma agents or drugs.

The active agents to be used in connection with the present invention may be any substance desired to be released from the chewing gum. The active agents, for which an accelerated rate of release is desired, are primarily substances with a limited water-solubility, typically below 10 g/100 ml inclusive of substances which are totally water-insoluble. Examples are medicines, dietary supplements, oral compositions, anti-smoking agents, highly potent sweeteners, pH adjusting agents, flavourings etc.

Other active ingedients is forinstance paracetamol, benzocaine, cinnarizine, menthol, carvone, coffeine, chlorhexidine-di-acetate, cyclizine hydrochloride, 1,8-cineol, nandrolone, miconazole, mystatine, aspartame, sodium fluoride, nicotine, saccharin, cetylpyridinium chloride, other quaternary ammoniumcompounds, vitamin E, vitamin A, vitamin D, glibenclamide or derivatives thereof, progesterone, acetylsalicylic acid, dimenhydrinate, cyclizine, metronidazole, sodium hydrogencarbonate, the active components from ginkgo, the active components from propolis, the active components from ginseng, methadone, oil of peppermint, salicylamide, hydrocortisone or astemizole.

Examples of active agents in the form of dietary supplements are for instance salts and compounds having the nutritive effect of vitamin B2 (riboflavin), B12, folinic acid, niacine, biotine, poorly soluble glycerophosphates, amino acids, the vitamins A, D, E and K, minerals in the form of salts, complexes and compounds containing calcium, phosphorus, magnesium, iron, zinc, copper, iodine, manganese, chromium, selenium, molybdenum, potassium, sodium or cobalt.

Furthermore, reference is made to lists of nutritients acccepted by the authorities in different countries such as for instance US code of Federal Regulations, Title 21, Section 182.5013.182 5997 and 182.8013-182.8997.

Examples of active agents in the form of compounds for the care or treatment of the oral cavity and the teeth, are for instance bound hydrogen peroxide and compounds capable of releasing urea during chewing.

Examples of active agents in the form of antiseptics are for instance salts and compounds of guanidine and biguanidine (for instance chlorhexidine diacetate) and the following types of substances with limited water-solubility: quaternary ammonium compounds (for instance ceramine, chloroxylenol, crystal violet, chloramine), aldehydes (for instance paraformaldehyde), compounds of dequaline, polynoxyline, phenols (for instance thymol, para chlorophenol, cresol) hexachlorophene, salicylic anilide compounds, triclosan, halogenes (iodine, iodophores, chloroamine, dichlorocyanuric acid salts), alcohols (3,4 dichlorobenzyl alcohol, benzyl alcohol, phenoxyethanol, phenylethanol), cf. furthermore Martindale, The Extra Pharmacopoeia, 28th edition, page 547-578; metal salts, complexes and compounds with limited water-solubility, such as aluminium salts, (for instance aluminium potassium sulfate $AlK(SO_4)_2,12H_2O$) and furthermore salts, complexes and compounds of boron, barium, strontium, iron, calcium, zinc, (zinc acetate, zinc chloride, zinc gluconate), copper (copper chloride, copper sulfate), lead, silver, magnesium, sodium, potassium, lithium, molybdenum, vanadium should be included; other compositions for the care of mouth and teeth: for instance; salts, complexes and compounds containing fluorine (such as sodium fluoride, sodiummonofluorophosphate, aminofluorides, stannous fluoride), phosphates, carbonates and selenium.

Cf. furthermore J. Dent.Res. Vol. 28 No. 2, page 160-171, 1949, wherein a wide range of tested compounds are mentioned.

Examples of active agents in the form of agents adjusting the pH in the oral cavity include for instance: acceptable acids, such as adipinic acid, succinic acid, fumaric acid, or salts thereof or salts of citric acid, tartaric acid, malic acid, acetic acid, lactic acid, phosphoric acid and glutaric acid and acceptable bases, such as carbonates, hydrogen carbonates, phosphates, sulfates or oxides of sodium, potassium, ammonium, magnesium or calcium, especially magnesium and calcium.

Examples of active agents in the form of anti-smoking agents include for instance: nicotine, tobacco powder or silver salts, for instance silver acetate, silver carbonate and silver nitrate.

In a further embodiment, the sucrose fatty acid esters may also be utilised for increased release of sweeteners including for instance the so-called highly potent sweeteners, such as for instance saccharin, cyclamate, aspartame, thaumatin, dihydrocalcones, stevioside, glycyrrhizin or salts or compounds thereof. For increased released of sweetener, the sucrose fatty acids preferable have a content of palmitate of at least 40% such as at least 50%.

Further examples of active agents are medicines of any type.

Examples of active agents in the form of medicines include coffeine, salicylic acid, salicyl amide and related substances (acetylsalicylic acid, choline salicylate, magnesium salicylate, sodium salicylate), paracetamol, salts of pentazocine (pentazocine hydrochloride and pentazocinelactate), buprenorphine hydrochloride, codeine hydrochloride and codeine phosphate, morphine and morphine salts (hydrochloride, sulfate, tartrate), methadone hydrochloride, ketobemidone and salts of ketobemidone (hydrochloride), beta-blockers, (propranolol), calcium antagonists, verapamil hydrochloride, nifedinpine as well as suitable substances and salts thereof mentioned in Pharm. Int., Nov.85, pages 267-271, Barney H. Hunter and Robert L. Talbert, nitroglycerine, erythrityl tetranitrate, strychnine and salts thereof, lidocaine, tetracaine hydrochloride, etorphine hydrochloride, atropine, insulin, enzymes (for instance papain, trypsin, amyloglucosidase. glucoseoxidase, streptokinase, streptodornase, dextranase, alpha amylase), polypeptides (oxytocin, gonadorelin, (LH.RH), desmopressin acetate (DDAVP), isoxsuprine hydrochloride, ergotamine compounds, chloroquine (phosphate, sulfate), isosorbide, demoxytocin, heparin.

Other active ingredients include beta-lupeol, Letigen®, Sildenafil citrate and derivatives thereof.

Dental products include Carbami, CPP Caseine Phospho Peptide; Chlorhexidine, Chlorhexidine di acetate, Chlorhexidine Chloride, Chlorhexidine di gluconate, Hexetedine, Strontium chloride, Potassium Chloride, Sodium bicarbonate, Sodium carbonate, Fluor containing ingredients, Fluorides, Sodium fluoride, Aluminium fluoride Ammonium fluoride, Calcium fluoride, Stannous fluoride, Other fluor containing ingredients Ammonium fluorosilicate, Potasium fluorosilicate, Sodium fluorosilicate, Ammonium monofluorphosphate, Calcium monofluorphosphate, Potassium monofluorphosphate, Sodium monofluorphosphate, Octadecentyl Ammonium fluoride, Stearyl Trihydroxyethyl Propylenediamine Dihydrofluoride,

Vitamins include A, B1, B2, B6, B12, Folin acid, niacin, Pantothensyre, biotine, C, D, E, K. Minerals include Calcium, phosphor, magnesium, iron, Zink, Cupper, Iod, Mangan, Crom, Selene, Molybden. Other active ingredients include: Q10®, enzymes. Natural drugs including Ginkgo Biloba, ginger, and fish oil. The invention also relates to use of migraine drugs such as Serotonin antagonists: Sumatriptan, Zolmitriptan, Naratriptan, Rizatriptan, Eletriptan; nausea drugs such as Cyclizin, Cinnarizin, Dimenhydramin, Difenhydrinat; hay fever drugs such as Cetrizin, Loratidin, pain relief drugs such as Buprenorfin, Tramadol, oral disease drugs such as Miconazol, Amphotericin B, Triamcinolonaceton; and the drugs Cisaprid, Domperidon, Metoclopramid. In a preferred embodiment the invention relates to the release of Nicotine and its salts

A further particularly preferred preparation according to the invention comprises up to 50 weight-%, preferably 0.1-10 weight-% active agent in the form of a solid dispersion hereof in a carrier, up to 60 weight-%, preferably approximately 20 weight-% of the carrier used to obtain the solid dispersion, 0.1-30 weight-%, preferably 0.1-10 weight-% solubilizer, 15-80 weight-%, preferably approximately 35 weight-% chewing gum base and up to 85 weight-%, preferably approximately 35 weight-% auxiliary substances and additives.

A particularly preferred preparation according to the invention comprises up to 50 weight-%, preferably 0.1-10 weight-% active agent admixed with at least one solubilzer, 15-80 weight-%, preferably approximately 35 weight-% chewing gum base, up to 85 weight-%, preferably approximately 50-60 weight-% auxiliary agents and additives and 0.1-30 weight-%, preferably approximately 5 weight-% solubilizer.

The invention further relates to a process for the preparation of a chewing gum composition, which process is characterised by preparing a chewing gum base on the basis of conventional chewing gum base constituents, wherein the resin portion consists of at least 25 weight-% of a resin selected among terpene resins, glycerol ester of polymerised rosin, pentaerythritol ester of polymerised rosin, pentaerythritol ester of wood or gum rosin, pentaerythritol ester of partially hydrogenated wood or gum rosin, glycerol ester of partially hydrogenated wood or gum rosin and high molecular weight polyvinyl acetate resins with a molecular weight of at least 30,000, and then in a conventional manner preparing a chewing gum composition while adding active agent, solubilizer and other conventional ingredients.

A particular embodiment according to the invention is characterised in that the active agent is intimately mixed with the solubilizer, optionally during heating, before adding to the chewing gum composition.

If a carrier is used, the process may advantageously be carried out by forming a solid dispersion of the active agent in a carrier prior to mixing the active agent with the solubilizer.

It is clear that the improved properties with respect to flavour obtained according to the present invention are of great importance when used with the active ingredients mentioned above. The active ingredients may be used in higher dosages, otherwise resulting in disadvantages according to side effects relating to the taste of the active ingredient.

According to a preferred embodiment of the invention, the sucrose fatty acid esters according to the invention are used for increasing the flavour properties of chewing gum formulations. As is well known in the art, chewing gum comprises an insoluble gum part and a water-soluble part. The gum bases generally contain elastomers, resins, fats, oils, waxes, emulsifiers and inorganic fillers.

The gum base comprising the sucrose fatty acid esters according to the present invention may be any conventional formulation and includes formulations wherein the chewing gum base contains about 5 weight-% to 50 weight-% elastomer which may be of natural or more preferred of synthetic origin, about 5 to about 55 weight-% elastomer plasticizer, about 0 to 50 weight-% filler, about 5 to about 35 weight-% softener, and optional minor amounts (about 1% or less) of miscellaneous ingredient such as antioxidants, colorants, etc.

According to the present text, the term softener is used for ingredients, which soften the gum or chewing gum formulation and encompass wax, fat, oil, emulsifiers, surfactants, solubilizers etc.

The gum base used in the chewing gum according to the invention is generally prepared in a conventional manner by heating and mixing the different ingredients such as elastomers, resins, inorganic fillers, waxes, fats, and emulsifiers etc.

The insoluble gum base generally comprises fats and oils, resins, elastomers, softeners, and inorganic fillers. The gum base may or may not include wax. The insoluble gum base can constitute approximately 5 to about 95 percent, by weight, of the chewing gum, more commonly, the gum base comprises 10 to about 50 percent of the gum, and in some preferred embodiments, 20 to about 35 percent, by weight, of the chewing gum.

Synthetic elastomers may include, but are not limited to, polyisobutylene with a gas pressure chromatography (GPC) average molecular weight of about 10,000 to about 1000 000, isobutylene-isoprene copolymer (butyl elastomer), styrene-butadiene copolymers having styrene-butadiene ratios of about 1:3 to about 3:1, polyvinyl acetate (PVA) having a GPC average molecular weight of about 2,000 to about 90,000, polyisoprene, polyethylene, vinyl acetate-vinyl laurate copolymer having vinyl laurate content of about 5 to about 50 percent by weight of the copolymer, and combinations thereof.

Preferred combinations include, but are not limited to polyisobutylene and styrene-butadiene, polyisobutylene and polyisoprene, polyisobutylene and isobutylene-isoprene copolymer (butyl rubber), polyisobutylene, styrene-butadiene copolymer, and isobutylene isoprene copolymer, and all of the above in admixture with polyvinyl acetate, vinyl acetate-vinyl laurate copolymers and admixtures thereof.

Preferred ranges are, for polyisobutylene, 50,000 to 80,000 GPC average molecular weight, for styrene-butadiene, 1:1 to 1:3 bound styrene-butadiene, for polyvinyl acetate, 3,000 to 80,000 GPC average molecular weight where the higher molecular weight polyvinyl acetates typically used in bubble gum base, and for vinyl acetate-vinyl laurate, a vinyl laurate content of 10-45 percent.

Natural elastomers may include natural rubber such as smoked or liquid latex and guayule as well as natural gums such as jelutong, lechi caspi, massaranduba balata, sorva, perillo, rosindinha, massaranduba chocolate, chicle, nispero, gutta hang kang, and combinations thereof. The preferred synthetic elastomer and natural elastomer concentrations vary depending on whether the chewing gum in which the base is used is adhesive or conventional, bubble gum or regular gum, as discussed below. Preferred natural elastomers include jelutong, chicle, massaranduba balata and sorva.

Resins should also be mentioned as a component forming part of a chewing gum base, said resins being used to obtain the right chewing consistency and as plasticizer for the elastomers of the chewing gum base.

Elastomers plasticizers may include, but are not limited to, natural rosin esters, often called estergums, such as glycerol esters of partially hydrogenated rosin, glycerol esters polymerized rosin, glycerol esters of partially dimerized rosin, glycerol esters of tall oil rosin, pentaerythritol esters of partially hydrogenated rosin, methyl and partially hydrogenated methyl esters of rosin, pentaerythritol esters of rosin; synthetics such as terpene resins derived from alpha-pinene, beta-pinene, and/or d-limonene, natural terpene resins; and any suitable combinations of the foregoing. The preferred elastomer plasticizers will also vary depending on the specific application, and on the type of elastomer which is used.

The fillers/texturizers that form part of the chewing gum base may include magnesium and calcium carbonate, sodium sulphate, ground limestone, silicate types such as magnesium and aluminium silicate, kaolin, clay, aluminium oxide, silicium oxide, talc, titanium oxide, mono-, di- and tri-calcium phosphates, cellulose polymers, such as wood, and combinations thereof.

The fillers/texturizers may also include natural organic fibres such as fruit vegetable fibres, grain, rice, cellulose and combinations thereof.

In a further embodiment, in addition to the sucrose polyesters, pursuant to the present invention, softeners/emulsifiers may include tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol monostearate, glycerol triacetate, lechithin, mono-, di- and triglycerides, acetylated monoglycerides, fatty acids (e.g. stearic, palmitic, oleic and linoleic acids), and combinations thereof.

Colorants and whiteners may include FD&C-type dyes and lakes, fruit and vegetable extracts, titanium dioxide, and combinations thereof.

Waxes may include synthetic waxes such as microcrystalline or paraffin waxes, or natural waxes such as carnauba, beeswax, candellila, or polyethylene wax.

In addition to a water insoluble gum base portion, a typical chewing gum composition includes a water soluble bulk portion and one or more flavouring agents as mentioned above. The water soluble portion can include bulk sweeteners, high intensity sweeteners, flavouring agents, softeners, emulsifiers, colours, acidulants, fillers, antioxidants, and other components that provide desired attributes.

The softeners, which are also known as plasticizers and plasticizing agents, generally constitute between approximately 0.5 to about 30% by weight of the chewing gum. The softeners may, in addition to including sucrose polyesters, include glycerin, lecithin, and combinations thereof. Aqueous sweetener solutions such as those containing sorbitol, hydrogenated starch hydrolysates, corn syrup and combinations thereof, may also be used as softeners and binding agents in chewing gum.

Bulk sweeteners include both sugar and sugarless components. Bulk sweeteners typically constitute 5 to about 95% by weight of the chewing gum, more typically constitute 20 to about 80% by weight, and more commonly, 30 to 60% by weight of the gum.

Sugar sweeteners generally include saccharide-containing components commonly known in the chewing gum art, but not limited to, sucrose, dextrose, maltose, dextrin, trehalose, D-tagatose, dried invert sugar, fructose, levulose, galactose, corn syrup solids, and the like, alone or in combination.

Sorbitol can be used as a sugarless sweetener. Additionally, sugarless sweeteners can include, but are not limited to, other sugar alcohols such as mannitol, xylitol, hydrogenated starch hydrolysates, maltitol, isomalt, erythritol, lactitol and the like, alone or in combination.

High intensity artificial sweeteners can also be used in combination with the above. Preferred sweeteners include, but are not limited to sucralose, aspartame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, sterioside and the like, alone or in combination. In order to provide longer lasting sweetness and flavour perception, it may be desirable to encapsulate or otherwise control the release of at least a portion of the artificial sweetener. Such techniques as wet granulation, wax granulation, spray drying, spray chilling, fluid bed coating, coascervation, encapsulation in yeast cells and fibre extrusion

may be used to achieve the desired release characteristics. The encapsulation can also be performed in another material such as resin.

Usage level of the artificial sweetener will vary greatly and will depend on such factors as potency of the sweetener, rate of release, desired sweetness of the product, level and type of flavour used and cost considerations. Thus, the active level of artificial sweetener may vary from 0.02 to about 8%. When carriers used for encapsulation are included, the usage level of the encapsulated sweetener will be proportionately higher. Combinations of sugar and/or sugarless sweeteners may be used in chewing gum. Additionally, the softener may also provide additional sweetness such as with aqueous sugar or alditol solutions.

If a low calorie gum is desired, a low caloric bulking agent can be used. Examples of low caloric bulking agents include polydextrose; Raftilose, Raftilin; Fructooligosaccharides (NutraFlora®); Palatinose oligosaccharide; Guar Gum Hydrolysate (Sun Fiber®); or indigestible dextrin (Fibersol®). However, other low calorie-bulking agent can be used.

Any of the usual elastomers can be used in a quantity of typically 5-50 weight-%. The elastomer may be of natural origin, for instance such as stated in Food and Drug Administration, CFR, Title 21, Section 172,615, as "Masticatory Substances of Natural Vegetable Origin", or synthetic elastomers, such as styrene butadiene gum (SBR), butyl gum (isobutylene isoprene copolymer), or polyisobutylene (as stated in the above section of FDA under Masticatory Substances, Synthetic).

Waxes and fats are conventionally used for the adjustment of the consistency and softening of the chewing gum base when preparing chewing gum bases. In connection with the present invention any conventionally used and suitable type of wax and fat may be used, such as for instance rice bran wax, polyethylene wax, petroleum wax (refined paraffin and micro crystalline wax), paraffin, beeswax, carnauba wax, candelilla wax, cocoa butter, degreased cocoa powder and any suitable oil or fat, as for instance completely or partially hydrogenated vegetable oils or completely or partially hydrogenated animal fats. In a preferred embodiment, the chewing gum is wax free. The wax of the general formulations may be replaced with hydrogenated oil or fat.

To soften the gum base further and to provide it with water binding properties, which gives the gum bases a pleasant smooth surface and reduces its adhesive properties, one or

more emulsifiers may usually be added. Mono and diglycerides of edible fatty acids, lactic acid esters and acetic acid esters of mono and diglycerides of edible fatty acids, acetylated mono and diglycerides, sugar esters of edible fatty acids, Na-, K-, Mg- and Ca-stearates, lecithin, hydroxylated lecithin and the like may be mentioned as examples of legal and conventionally used emulsifiers added to the chewing gum base. In case of the presence of an active ingredient, the formulation may comprise certain specific emulsifiers and/or solubilizers in order to disperse and release the active ingredient.

In addition to the sucrose fatty acid ester, emulsifiers, which are conventionally used in quantities of 0-18 weight-%, preferably 0-12 weight-% of the gum base, may be present.

Furthermore, the chewing gum base may optionally contain the usual additives, such as antioxidants, for instance butylated hydroxytoluene (BHT), butyl hydroxyanisol (BHA), propylgallate and tocopherols as well as preservatives and colorants.

The chewing gum may also comprise the following surfactants and/or sulubilizers, especially when active ingredients are present. As examples of types of surfactants to be used as solubilizers in a chewing gum composition according to the invention reference is made to H.P. Fiedler, Lexikon der Hilfstoffe für Pharmacie, Kosmetik und Angrenzende Gebiete, page 63-64 (1981) and the lists of approved food emulsifiers of the individual countries.

Both anionic, cationic, amphoteric, and nonionic solubilizers can be used, but usually the solubilizer used is either anionic or nonionic as mainly such solubilizers are approved for use in food or medicines. In cases where the active agent is reactive it is usually an advantage to use a nonionic solubilizer as such are not very reactive and therefore do not affect the stability of the active agent unfavourably.

Suitable solubilizers include lecithines, polyoxyethylene stearate, polyoxyethylene sorbitan fatty acid esters, fatty acid salts, mono and diacetyl tartaric acid esters of mono and diglycerides of edible fatty acids, citric acid esters of mono and diglycerides of edible fatty acids, saccharose esters of fatty acids, polyglycerol esters of fatty acids, polyglycerol esters of interesterified castor oil acid (E476), sodium stearoyllatylate, sodium lauryl sulfate and sorbitan esters of fatty acids, which solubilizers are all known for use as food emulsifiers, and polyoxyethylated hydrogenated castor oil (for instance such sold under the trade name CREMOPHOR), blockcopolymers of ethylene oxide and propylene oxide (for instance as sold under the trade name PLURONIC or the trade name POLOXAMER),

polyoxyethylene fatty alcohol ethers, polyoxyethylene sorbitan fatty acid esters, sorbitan esters of fatty acids and polyoxyethylene steraric acid ester, all known in the EEC for use as pharmaceutical-cosmetical emulsifiers.

Particularly suitable solubilizers are polyoxyethylene stearates, such as for instance polyoxyethylene(8)stearate and polyoxyethylene(40)stearate, the polyoxyethylene sorbitan fatty acid esters sold under the trade name TWEEN, for instance TWEEN 20 (monolaurate), TWEEN 80 (monooleate), TWEEN 40 (monopalmitate), TWEEN 60 (monostearate) or TWEEN 65 (tristearate), mono and diacetyl tartaric acid esters of mono and diglycerides of edible fatty acids, citric acid esters of mono and diglycerides of edible fatty acids, sodium stearoyllatylate, sodium laurylsulfate, polyoxyethylated hydrogenated castor oil, blockcopolymers of ethylene oxide and propyleneoxide and polyoxyethylene fatty alcohol ether. The solubilizer may either be a single compound or a combination of several compounds. The expression "solubilizer" is used in the present text to describe both possibilities, the solubilizer used must be suitable for use in food and/or medicine.

In the presence of an active ingredient the chewing gum may preferably also comprise a carrier known in the art.

In a preferred embodiment according to the invention, the palmitate/stearate sucrose fatty acid ester is used in oral compositions, including chewing gum, which further comprises an active ingredient. The palmitate/stearate sucrose fatty acid ester may then help in masking an otherwise undesired taste from the active ingredient. Examples of active agents in the form of compounds for the care or treatment of the oral cavity and the teeth, are for instance bound hydrogen peroxide and compounds capable of releasing urea during chewing.

Examples of active agents in the form of antiseptics are for instance salts and compounds of guanidine and biguanidine (for instance chlorhexidine diacetate) and the following types of substances with limited water-solubility: quaternary ammonium compounds (for instance ceramine, chloroxylenol, crystal violet, chloramine), aldehydes (for instance paraformaldehyde), compounds of dequaline, polynoxyline, phenols (for instance thymol, para chlorophenol, cresol) hexachlorophene, salicylic anilide compounds, triclosan, halogenes (iodine, iodophores, chloroamine, dichlorocyanuric acid salts), alcohols (3,4 dichlorobenzyl alcohol, benzyl alcohol, phenoxyethanol, phenylethanol), cf. furthermore Martindale, The Extra Pharmacopoeia, 28th edition, page 547-578; metal salts, complexes and compounds with limited water-solubility, such as aluminium salts, (for

instance aluminium potassium sulphate $AlK(SO_4)_2,12H_2O$) and furthermore salts, complexes and compounds of boron, barium, strontium, iron, calcium, zinc, (zinc acetate, zinc chloride, zinc gluconate), copper (copper chloride, copper sulphate), lead, silver, magnesium, sodium, potassium, lithium, molybdenum, vanadium should be included; other compositions for the care of mouth and teeth: for instance; salts, complexes and compounds containing fluorine (such as sodium fluoride, sodiummonofluorophosphate, aminofluorides, stannous fluoride), phosphates, carbonates and selenium.

Confer furthermore J. Dent.Res. Vol. 28 No. 2, page 160-171, 1949, wherein a wide range of tested compounds are mentioned.

Examples of active agents in the form of agents adjusting the pH in the oral cavity include for instance: acceptable acids, such as adipinic acid, succinic acid, fumaric acid, or salts thereof or salts of citric acid, tartaric acid, malic acid, acetic acid, lactic acid, phosphoric acid and glutaric acid and acceptable bases, such as carbonates, hydrogen carbonates, phosphates, sulphates or oxides of sodium, potassium, ammonium, magnesium or calcium, especially magnesium and calcium.

It is clear that the improved properties with respect to flavour obtained according to the present invention are of great importance when used with the active ingredients mentioned above.

In one embodiment, where the preparation according to the invention comprises an active ingredient, up to 50 weight-%, preferably 0.1-10 weight-% active agent may be in the form of a solid dispersion hereof in a carrier, up to 60 weight-%, preferably approximately 20 weight-% of the carrier used to obtain the solid dispersion, 0.1-30 weight-%, preferably 0.1-10 weight-% solubilizer, 15-80 weight-%, preferably approximately 35 weight-% chewing gum base and up to 85 weight-%, preferably approximately 35 weight-% auxiliary substances and additives.

The invention further relates to a process for the preparation of a chewing gum composition, which process is characterised by preparing a chewing gum base on the basis of conventional chewing gum base constituents.

The formulation of the chewing gum base depends on the type of chewing gum desired as described above or the required type of structure. Suitable raw materials for the gum base

comprise substances according to U.S. Chewing Gum Base Regulations - Code of Federal Regulations, Title 21, Section 172.615.

It is a particular advantage of the invention that the chewing gum composition can be prepared using conventional ingredients, conventional equipment and conventional methods of preparation.

When the active agent has been incorporated in the chewing gum carrier, this product may be of any known type, such as bits, optionally provided with a dragée, and sticks or chewing gum of any other desired form. The chewing gum pieces may be coated with a type of wax, a film coating or a conventional so-called candy coat based on sugar-containing or sugar free substances.

A single piece of chewing gum usually weighs between 0.4 and 20.0 g. The following Table indicates the preferred intervals for the different product types:

Chewing gum bits	500-3,500 mg
Coated chewing gum	600-6,000 mg
Chewing gum sticks	1,000-5,000 mg

When the individual ingredients forming part of a chewing gum composition according to the invention are mentioned in singular, such mention also comprises a combination of several such ingredients, apart from instances where one particular ingredient is mentioned.

In a further embodiment, bubble gum formulation may also be prepared with the sucrose fatty acids according to the invention.

The invention is illustrated in more details below by means of the Examples, which are not limiting for the present invention.

Examples of chewing gum bases:

Preparation of a chewing gum base suitable for an ordinary chewing gum.

Synthetic elastomer	15%

Polyvinyl acetate (PVA)	22%
Elastomer plasticizer	26%
Sucrose fatty acid ester	3%
Filler	14%
Softeners	20%

Preparation of a chewing gum base suitable for a chewing gum comprising an active ingredient.

Elastomers	4 weight-%
Terpene resin	28 weight-%
PVA	29 weight-%
Emulsifier	6 weight-%
Sucrose fatty acid ester	2 weight-%
Waxes	31 weight-%

The elastomer is masticated in a conventional mixer for the preparation of chewing gum and gum base while being heated to 110-130°C and terpene resin and low molecular weight PVA are added slowly in small portions. Finally waxes and emulsifier are added. To ensure a homogenous base it is important that all the ingredients are added in small portions and that the subsequent portions are not added until the preceding portion is mixed.

Preparation of Chewing Gum

Examples of a chewing gum prepared according to the present invention:

Basic Formulation 1, comprising an active ingredient.

Gum base	35 weight-%
Sorbitol powder	10 weight-%
Hydrogenated glucose syrup	10 weight-%
Active agent if desired	0.01-30 weight-%
Solubilizer	0-20 weight-%
Optional flavour	1.9 weight-%

Optional additional sorbitol powder q.s. 100 weight-%

The chewing gum pieces are prepared in the manner conventional for the preparation of chewing gum and using a conventional apparatus for the preparation of chewing gum.

The chewing gum base is softened in a conventional chewing gum mixer. The other ingredients are admixed one by one preferable in the order mentioned. A possible active agent may be admixed separately or in the form of a pre-mixture or in a solution. Depending on the state of the ingredients and their melting point, such pre-mixture may be a simple mixture of two or more powders, a mixture of one or more powders in one or more liquids or a mixture of more liquids at ordinary, increased or lower temperature. To ensure a good dispersion of the ingredients it may, especially when adding very small quantities of one or more of the components of the pre-mixture, be an advantage to add these as a liquid mixture or a solution where this is possible.

Apart from mixing the gum base first, the order of the admixture is not critical. However, the mixing should be of a duration long enough to ensure a sufficiently good dispersion of the ingredients in the chewing gum mass. Optionally supplementary flavourings are usually added lastly followed by mixing for 2 to 3 minutes.

Upon completion of the mixing, the homogenous chewing gum mass is removed from the mixer and cut out and left to cool in small pieces or is extruded to a thin sheet, which is led through a cooling apparatus. The thin sheet is rolled on a conventional chewing gum rolling system and cut into bits of appropriate form and size.

The bits are left to harden for two to five days and are then separated by tumbling in a conventional dragée pan. Subsequently, the bits are completed by applying a thin polishing layer by film coating or a dragée coating is provided.

LEGENDS TO FIGURES

Figure 1. Shows a diagram demonstrating the flavour intensity of menthol as function of time in a formulation comprising sucrose fatty acid ester compared to a standard formulation comprising menthol.

Figure 2. Shows a diagram demonstrating the intensity of cooling as a function of time in a formulation comprising sucrose fatty acid ester compared to a standard formulation.

Figure 3. Shows a diagram of a comparison test wherein intensity of cooling as a function of time, in addition to a formulation according to the present invention, are shown for formulations comprising a selection of conventional cooling agents (A, B, and C), a formulation comprising an emulsifier and a standard formulation.

Example 1

Study with use of a conventional sucrose fatty acid ester for evaluating flavour and stickiness.

The sucrose fatty acid esters were added in different amounts and with different HLB values in gum base and in a chewing gum (Peppermint).

In the present pilot study, the standard gum base with which the formulations comprising sucrose fatty acid ester are compared comprises 8.9 % mono-diglycerides. The sucrose containing formulations further comprised the sucrose fatty acid ester as additional emulsifier. Accordingly, it is expected that the formulations further comprising sucrose fatty acid ester as emulsifier should have improved properties compared to the standard formulation.

Type	Stearate/Palmitate (70/30)	HLB (Hydrophile Lipophile Balance)
SP 30	(30% of monoester)	6
SP 40	(40% of monoester)	8
SP 70	(70% of monoester)	15

Trial no.	Modification	Stickiness (Newton)	Hardness (Newton (day 3))	Notes
1	GB added 0.5 % SP 30	31.8	19.7	Strong taste at start, tough and dry texture, greasy mouthfeel.
2	GB added 1 % SP 30	25.6	18.7	Tough and dry texture, greasy, dead chew
3	GB added 0.5 % SP 40	30.4	16.4	Big volume, greasy, dead chew
4	GB added 1 % SP 40	22.5	16.3	Juicy in the initial phase, greasy, creak, dead chew
5	GB added 0.5 % SP 70	23.1	15.7	Strong taste, greasy mouthfeel, off notes, dead chew
6	GB added 1 % SP 70	9.9	16.1	Stronger taste, greasy mouthfeel, off notes, tough and dead chew
7	CG added 0.5 % SP 30	31.1	8.2	Strong juicy taste, off notes, softens fast but dissolves a bit, dead chew
8	CG added 1 % SP 30	-	10.8	Dissolves
9	CG added 0.5 % SP 40	23.7	8.1	Tough start, strong juicy taste, off notes, greasy surface, dead chew
10	CG added 1 % SP 40	-	8.3	Dissolves
11	CG added 0.5 % SP 70	-	8.6	Dissolves

12	CG added 1 % SP 70	-	8.2	Dissolves
13	STD	21.9/26.6	9.2	good start, soft and pleasant chew

GM: Gum base

CG: Chewing gum

Conclusion:

The results showed no positive effect regarding stickiness in chewing gum. There are some trials with lower stickiness than the standard but the texture is also changed to a dry and dead chew. The flavour release seems slightly improved and may be due to the increased content of emulsifier.

Example 2.

Testing of prior art sucrose fatty acid esters obtained for Sisterna and consisting of 70% stearate and 30% palmitate.

The following formulations are evaluated.

Gum base

Substitute (Weight by weight with existing emulsifier)	Type SE	Amounts (W/W %)	Flavour
X	SP 10	1,5	Menthol
X	SP 10	3,0	Menthol
X	SP 30	1,5	Menthol
X	SP 30	3,0	Menthol
X	SP 10:SP 30 (1:3)	1,5	Menthol
X	SP 10:SP 30 (1:3)	3,0	Menthol
Existing emulsifier removed	SP 10:SP 30 (1:3)	3,0	Menthol
X	SP 10	0,5	Eucalyptus
X	SP 30	0,5	Eucalyptus

X	SP 10:SP 30 (1:3)	0,5	Eucalyptus

SE: Sucrose fatty acid ester

Chewing gum

Substitute (Weight by weight with existing bulk sweetener)	Type SE	Amounts (W/W %)	Flavour
X	SP 10:SP 30 1:3	0,5	Eucalyptus
X	SP 10:SP 30 1:3	1,5	Eucalyptus
X	SP 10:SP 30 1:3	3,0	Eucalyptus

SE: Sucrose fatty acid ester

Conclusion:

The conclusion by the test persons is that the sucrose fatty acid ester results in a less fresh taste compared with standard and that the sucrose fatty acid esters are not suitable for increasing flavour release or intensity.

Example 3

Comparison test with sucrose fatty acid ester according to the present invention.

The results are evaluated as described below by a taste panel.

Time-intensity Report:

Products:

1. Standard formulation (Stimorol® Peppermint).
2. The standard formulation comprising 3 weight-% sucrose fatty acid ester according to the present invention, Palmitate/stearate 80/20, monoester content 75% (PS750). The test formulation is identical with the standard except than 3 weight-% emulsifier is replaced with 3 weight -% sucrose fatty acid ester.

Taste panel:

The taste panel comprised 9 skilled persons.

Elapsed time:

One hour per person in the panel + time used by the panel leader, a total of 22 hours.

Procedure:

This test is analysed in the Sensorik Laboratorium of Dandy which consist of ten individual test boxes according to ISO 8589. The products are served at room temperature in 40 millilitre plastic cups encoded with a randomised, three-digit number.

The products are tested with the following interval (seconds):
5, 15, 30, 45, 60, 75 90, 105, 120, 135, 150, 165, 180, 240, 300, 360, and 420.

There is a 3 minutes pause between each of the products being tested. Each test is repeated. FIZZ (French Biosystem) is used to collect and compute the data.

The results are shown in figures 1-3.

Conclusion:

The formulation comprising sucrose fatty acid ester has a significantly higher flavour release from 5 seconds to 4 minutes (inclusive) than the standard formulation. This also appears from Figure 1.

From Figure 2 it appears that also the intensity of cooling is increased with the sucrose fatty acid ester according to the present invention.

From Figure 3 it is furthermore clear that the formulation comprising the sucrose fatty acid ester is superior compared with other cooling agents (A, B, and C) and also with a formulation in which 3% enzymatic hydrolysed soya lecithine (Emulsifier) is added instead of 3% sucrose fatty acid ester.

Example 4

A pilot study with the strawberry and pineapple flavour in chewing gum.

The strawberry flavour was clearly increased and some of the notes of the pineapple flavour were also increased indicating that the sucrose fatty acid esters according to the invention may alter the overall taste sensation.

Furthermore, it has been shown that the addition of sucrose fatty acids also adds volume to the gum base, which is a highly desired property.

Example 5.

Sensoric evaluations:

The following formulations are evaluated:

0,5 %, 1,5% and 2,5% PS300 in gum base; 0,5 %, 1,5% and 2,5% PS500 in gum base and 0,5 %, 1,5% and 2,5% PS450 in gum base, where

PS300: Palmitate/stearate 80/20 30% monoester.
PS450: Palmitate/stearate 50/50 50% monoester.
PS500: Palmitate/stearate 80/20 50% monoester.

They have all been evaluated in the following flavour systems; Fruit, Mint and combination of fruit and mint.

Fruit:
Higher flavor intensity, better harmoni between flavaor and acid, more tast of fruit. The overall flavor picture is changed compared to sample without sucrose fatty acid ester.

Mint:
Higher flavour intensity and more cooling. The overall flavour picture is changed compared to sample without sucrose fatty acid ester.

Mint/fruit:

More cooling, higher flavour intensity. The overall flavour picture is changed compared to sample without sucrose fatty acid ester.

Example 6

Evaluation of stickiness:

Trial no	W/W % SE	Flavour system	Stickiness (Newton) Mean±SD
14	0	Fruit/Mint	5,08
15	0,5 PS300	Fruit/Mint	3,33
16	0,5 PS500	Fruit/Mint	3,31
17	0,5 PS450	Fruit/Mint	2,30
18	0	Mint	5,20
19	1,8 PS300	Mint	3,74
20	1,8 PS500	Mint	1,72
21	1,8 PS450	Mint	3,43
22	0	Fruit	9,46
23	2,5 PS300	Fruit	4,74
24	2,5 PS500	Fruit	5,64
25	2,5 PS450	Fruit	5,43

SE: sucrose fatty acid ester

Conclusion:

In general it can be seen, that adding sucrose fatty acid ester to the formulation, results in a lower stickiness.

Example 7

Increased release of nicotine from formulation similar to commercial available nicotine chewing gum.

Formulation 1

A chewing gum similar to the commercially available 2 mg Nicotinell ® (tuttisweet) was prepared in laboratory scale to avoid any differences due to high scale production/laboratory scale production between the test products.

Formulation 2

A formulation similar to formulation 2 except that 3% monodiglycerid of the commercial formulation is replaced with 3 % sucrose fatty acid ester, 80/20 palmitate/stearate and a monoester content of 75%.

The release of nicotine is tested on a conventional chewing machine of the six chamber type. The release is calculated based on the basis of the nicotine still contained in the formulation at the selected time of chewing.

The results are shown below as mean values (N=3)

	Release in %	
	Standard	sucrose ester
after 10 minutes	50.56	61.35
after 20 minutes	71.95	75.89
after 30 minutes	80.71	82.69

REFERENCES

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Pharm. Int., Nov.85, pages 267-271, Barney H. Hunter and Robert L. Talbert

CLAIMS

1. Use of a fatty acid sucrose ester wherein at least 40% of the fatty acid is palmitate for increasing release of an active ingredient from a product selected from beverages, foodstuff, including functional foods, candy, and oral pharmaceutical compositions including products for the oral cavity.

2. Use according to claim 1 wherein the content of palmitate in the sucrose fatty acids ester is at least 50%, such as at least 60%, preferable at least 70%, more preferred at least 80%, still more preferred at least 90%, most preferred about 100%.

3. Use according to any of the preceding claims wherein the content of palmitate is between 50% and 100%, such as between 60% and 95%, preferable between 75% and 90% such as about 80%.

4. Use according to any of the preceding claims wherein the sucrose ester further comprises stearate.

5. Use according to any of the preceding claims wherein the sucrose fatty acid ester comprises palmitate and stearate as the only fatty acid esters.

6. Use according to any of the preceding claims wherein the sucrose fatty acid ester comprises at least 10% monoesters, such as at least 20%, preferable at least 30%, more preferred at least 40%, still more preferred at least 50%, most preferred about 60% monoesters.

7. Use according to any of the preceding claims wherein the sucrose fatty acid ester comprises at least 50% monoesters, such as at least 60%, preferable at least 70%, more preferred at least 80%, still more preferred at least 90%, most preferred about 100% monoesters.

8. Use according to any of the preceding claims wherein the active ingredient is a flavour.

9. Use according to claim 8 wherein the increased release of the flavour results in increased flavour properties.

10. Use according to claim 9 wherein the increased property relates to one or more effects selected from increased intensity of the flavour and cooling.

11. Use according to any of claims 8-10 wherein the flavour is a freeze-dried natural vegetable component.

12. Use according to claim 11 wherein the flavour is a freeze-dried fruit.

13. Use according to any of the preceding claims wherein the active ingredient comprises at least one flavour and a pharmaceutically active ingredient.

14. Use according to any of the preceding claims wherein the sucrose fatty acid ester further reduces the tac to the teeth and/or other surfaces.

15. 15. Use according to any of the preceding claims wherein the sucrose fatty acid ester further provides increased volume to the product.

16. Use according to any of the preceding claims wherein the sucrose fatty acid ester is used in an amount of from about 0.01 to 30% by weight of the total composition preferably in an amount from 0.1% to 20% by weight.

17. Use according to any of the preceding claims wherein the product is a candy.

18. Use according to any of the preceding claims wherein the product is a chewing gum.

19. Use according to any of any of the preceding claims wherein the product is an oral pharmaceutical composition.

20. Use according to any of any of the preceding claims wherein the product comprises an active ingredient which is a pharmaceutically active ingredient including ingredients for local treatment on the oral cavity or oral hygienic ingredients.

21. Use of a fatty acid sucrose ester according to any of the preceding claims for the preparation of a chewing gum.

22. Use according to claim 21 wherein the sucrose fatty acid ester is added to the gum base of the chewing gum in an amount of about 0.03 to 30% by weight, preferable from 0.5 to 10 % by weight, more preferred in an amount of from 1-3% by weight, such as about 2% by weight of the gum base.

23. A chewing gum formulation having increased release of an active ingredient comprising
a) an insoluble gum base;
b) a water soluble portion;
c) a flavour
d) at least 0,01% fatty acid sucrose ester wherein at least 40% of the fatty acid is palmitate.

24. A chewing gum according to claim 23 wherein the content of palmitate in the sucrose fatty acids ester is at least 50%, such as at least 60%, preferable at least 70%, more preferred at least 80%, still more preferred at least 90%, most preferred about 100%.

25. A chewing gum according to claim 23 wherein the content of palmitate is between 50% and 100%, such as between 60% and 95%, preferable between 75% and 90% such as about 80%.

26. A chewing gum according to any of the claims 23-25 wherein the sucrose ester further comprises stearate.

27. A chewing gum according to any of the claims 23-26 wherein the sucrose fatty acid ester comprises palmitate and stearate as the only fatty acid esters.

28. A chewing gum according to any of the claims 23-27 wherein the increased release property relates to one or more effects selected from increased intensity of the flavour and cooling.

29. A chewing gum according to claim 28 wherein the flavour intensity is increased compared to a similar formulation without the sucrose fatty acid ester.

30. A chewing gum according to any of claims 23-29 wherein the sucrose fatty acid ester further reduces the tac to the teeth and/or other surfaces.

31. A chewing gum according to any of claims 23-30 wherein the sucrose fatty acid ester further provides increased volume to the product.

32. A chewing gum according to any of claims 23-31 wherein the sucrose fatty acid ester is used in an amount of from about 0.01 to15% by weight of the total formulation.

33. A chewing gum according to any of claims 23-32 wherein the sucrose fatty acid ester is used in an amount of from about 0.1 to 5% by weight of total formulation

34. The chewing gum formulation according to any of claims 23-33 wherein the sucrose fatty acid ester comprises at least 10% monoesters, such as at least 20%, preferable at least 30%, more preferred at least 40%, still more preferred at least 50%, most preferred at least 60% monoesters.

35. The chewing gum formulation according to any of claims 23-34 wherein the formulation includes one or more ingredients selected from a bulk sweetener, a high intensity sweetener, an emulsifier, a softener, an elastomer plasticizer, an elastomer, a mono-diglyceride.

36. A chewing gum according to any of claims 23-35 wherein the sucrose fatty acid ester is added to the gum base.

37. A chewing gum according to any of claims 23-36 which is a bubble gum.

38. A foodstuff, a candy or a beverage comprising a fatty acid sucrose ester wherein at least 40% of the fatty acid is palmitate, the foodstuff, candy or beverage having increased release of flavour compared with a similar product not comprising the fatty acid sucrose ester.

39. A method for increasing the release of an active ingredient in a product selected from beverages, foodstuff, including functional foods, candy, and oral pharmaceutical

compositions including products for the oral cavity comprising adding to said product a fatty acid sucrose ester wherein at least 40% of the fatty acid is palmitate.

40. A method according to claim 39 wherein the content of palmitate in the sucrose fatty acids ester is at least 50%, such as at least 60%, preferable at least 70%, more preferred at least 80%, still more preferred at least 90%, most preferred about 100%.

41. A method according to any of claims 39- 40 wherein the content of palmitate is between 50% and 100%, such as between 60% and 95%, preferable between 75% and 90% such as about 80%.

42. A method according to any of claims 39- 41 wherein the sucrose ester further comprises stearate.

43. A method according to any of claims 39- 42 wherein the sucrose fatty acid ester comprises palmitate and stearate as the only fatty acid esters.

44. A method according to any of 39- 43 claims wherein the sucrose fatty acid ester comprises at least 10% monoesters, such as at least 20%, preferable at least 30%, more preferred at least 40%, still more preferred at least 50%, most preferred about 60% monoesters.

45. A method according to any of claims 39- 44 wherein the sucrose fatty acid ester comprises at least 50% monoesters, such as at least 60%, preferable at least 70%, more preferred at least 80%, still more preferred at least 90%, most preferred about 100% monoesters.

46. A method according to claims 39- 45 wherein the active ingredient is a flavour.

47. A method according to claim 46 wherein the increased release of the flavour results in increased flavour properties.

48. A method according to claim 47 wherein the increased property relates to one or more effects selected from increased intensity of the flavour and cooling.

49. A method according to any of claims 47-48 wherein the flavour is a freeze-dried natural vegetable component.

50. A method according to claim 49 wherein the flavour is a freeze-dried fruit.

51. A method according to any of claims 39- 50 wherein the active ingredient comprises at least one flavour and a pharmaceutically active ingredient.

52. A method according to any of claims 39- 51 wherein the sucrose fatty acid ester further reduces the tac to the teeth and/or other surfaces.

53. A method according to any of the claims 39- 52 wherein the sucrose fatty acid ester further provides increased volume to the product.

54. A method according to claims 39- 53 wherein the sucrose fatty acid ester is used in an amount of from about 0.01 to 30% by weight of the total composition preferably in an amount from 0.1% to 20% by weight.

55. A method according to any of claims 39- 54 wherein the product is a candy.

56. A method according to any of the claims 39- 55 wherein the product is a chewing gum.

57. A method according to any of any of claims 39- 56 wherein the product is an oral pharmaceutical composition.

58. A method according to any of any of claims 39- 57 wherein the product comprises an active ingredient which is a pharmaceutical active ingredient including ingredients for local treatment on the oral cavity and oral hygienic ingredients.

59. A method for the preparation of a chewing gum according to any of claims 23-37 having increased release of an active ingredient comprising adding to said chewing gum a fatty acid sucrose ester as disclosed in any of claims 1-22.

60. A method according to claim 59 wherein the sucrose fatty acid ester is added to the gum base of the chewing gum in an amount of about 0.03 to 30% by weight, preferable from 0.5 to 10 % by weight, more preferred in an amount of from 1-3% by weight, such as about 2% by weight of the gum base.

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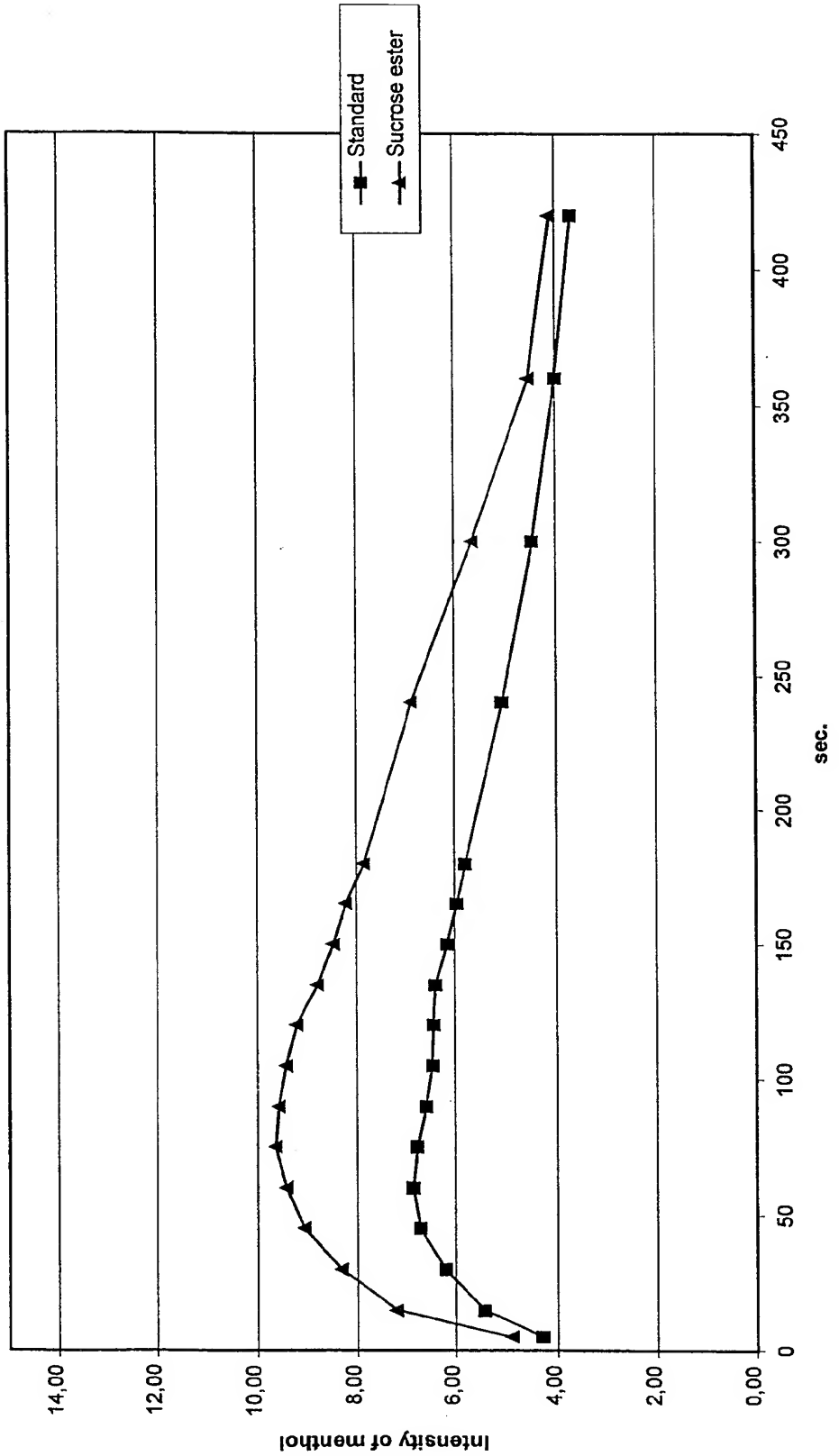
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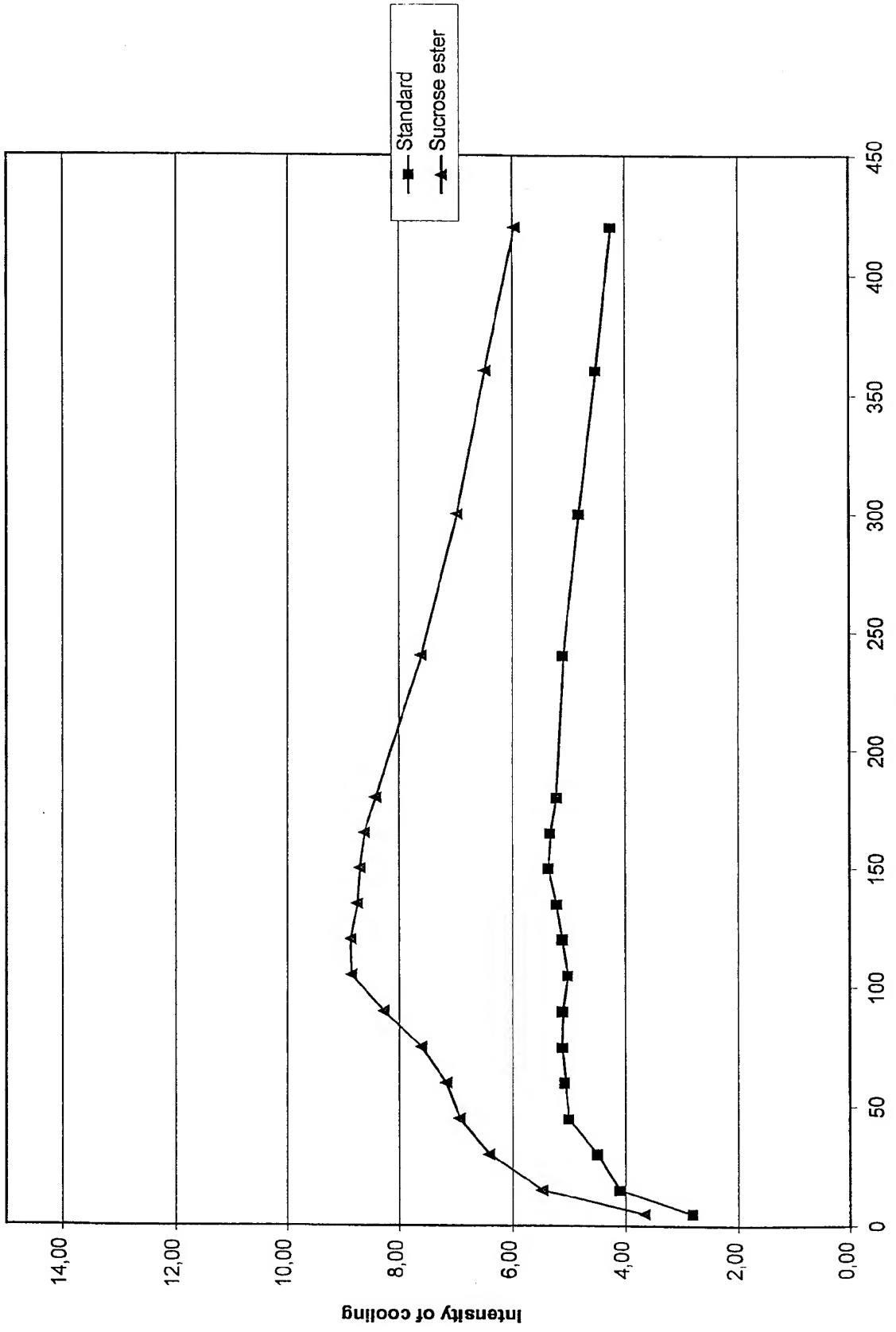
Fig. 1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Sucrose ester
Intensity of cooling
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12,00
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350
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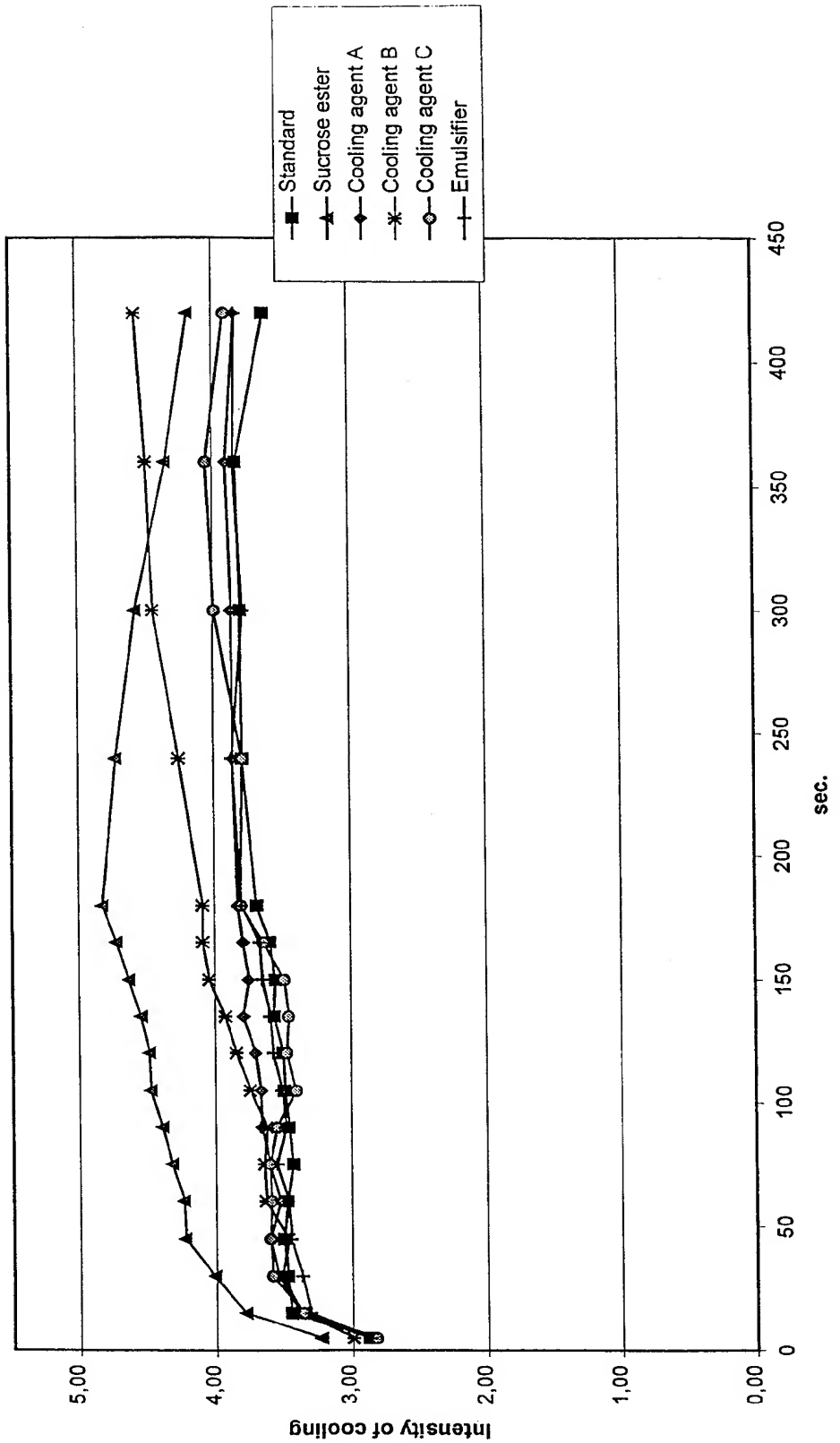
sec.

Fig. 2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Sucrose ester
Cooling agent A
Cooling agent B
Cooling agent C
Emulsifier
Intensity of cooling
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4,00
3,00
2,00
1,00
0,00
0
50
100
150
200
250
300
350
400
450
sec.

Fig. 3

INTERNATIONAL SEARCH REPORT

In tional Application No
PCT/DK 99/00598

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A23G3/30 A23L1/22 A23L1/308 A23G3/00 A61K47/26

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 230 332 A (N.V. SANICO) 29 July 1987 (1987-07-29) page 3, line 9 - line 13; claims; example	1-3,6,7, 16,19, 20, 39-41, 45,46, 55,58,59
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 February 2000	24/02/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

In tional Application No
PCT/DK 99/00598

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	WO 90 04926 A (WM WRIGLEY JR. COMPANY) 17 May 1990 (1990-05-17) page 2, line 8 - line 15; claims 9,10,15; examples	1-61
A	EP 0 446 170 A (WARNER-LAMBERT COMPANY) 11 September 1991 (1991-09-11)	

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